

January 2014

2013 MEETING OF THE COUNCIL OF FELLOWS  
OF THE COLLEGIUM RAMAZZINI

place: Carpi, Italy  
date: 26 October 2013  
time: 9:00 a.m.

Fellows present:

ANDERSON, HENRY  
ASHFORD, NICHOLAS  
ASSENATO, GIORGIO  
BAUR, XAVER  
BELPOGGI, FIORELLA  
BINGHAM, EULA  
BRAUTBAR, NACHMAN  
BULAT, PETAR  
CASTELEYN, LUDWINE  
CASTLEMAN, BARRY  
CHEN, JIA  
CHERNIACK, MARTIN  
COMBA, PIETRO  
CRANOR, CARL  
CRESPI, MASSIMO  
DE ROSA, CHRISTOPHER  
DOBBIN, DENNY  
DUFFY, RICHARD  
FINKELSTEIN, YORAM  
FORASTIERE, FRANCESCO  
FRANK, ARTHUR  
FROINES, JOHN  
FRONEBERG, BRIGITTE  
FUCIC, ALEKSANDRA  
GRANDJEAN, PHILIPPE  
HEINZOW, BIRGER  
HOEL, DAVID  
HRYHORCZUK, DANIEL  
JAROSINSKA, DOROTA  
JARVHOLM, BENGT  
JEEBHAY, MOHAMED  
JENSEN, TINA KOLD  
KOVATS, SARI  
LAMBERTINI, LUCA  
LANDRIGAN, PHIL  
LERMAN, YEHUDA  
LIOY, PAUL  
LUCCHINI, ROBERTO  
McDIARMID, MELISSA  
MELIUS, JAMES  
MIRER, FRANKLIN  
NATALI, PIER GIORGIO  
NGUYEN BICH, DIEP  
NORDBERG, GUNNAR

NOWAK, DENNIS  
OLIVER, CHRISTINE  
PELCLOVA, DANIELA  
RAMPAL, KRISHNA GOPAL  
RICE, CAROL  
RICHTER, ELIHU  
RINGEN, KNUT  
RITZ, BEATE  
RUCHIRAWAT, MATHUROS  
SASS, JENNIFER  
SILBERGELD, ELLEN  
SOFFRITTI, MORANDO  
SOSKOLNE, COLIN  
SOTO, ANA  
TAKAHASHI, KEN  
TARKOWSKI, STANISLAW  
TEITELBAUM, DANIEL  
THORBORG, MARINA  
VAN DAMME, KAREL  
VON BRAUN, MARGRIT  
WEDEEN, RICHARD  
WICKRAMATILLAKE, HEMANTHA  
WOLFF, MARY  
WRIGHT, ROBERT  
XINTARAS, CHARLES

Total number of Fellows present: 69

In attendance:

Enrico Campedelli, Mayor of Carpi  
Kathryn Knowles, Collegium Ramazzini General Secretariat  
Jill Brazier, Honorary Fellow

The President welcomed Fellows to the 31<sup>st</sup> edition of Ramazzini Days and declared the meeting open. He then introduced the Mayor of Carpi who gave a brief address in Italian, translated by Kathryn Knowles.

*Mayor Campedelli welcomed Fellows back to Carpi, noting that Ramazzini Days is always one of the most important events of the year. The Mayor thanked the Collegium Ramazzini for all he learned in the last 10 years about public health and the environment. He is certain that his successor will continue to enjoy this important collaboration. He then presented special parting gifts to President Landrigan and Secretary General Soffritti: two bottles of balsamic vinegar from the Town of Carpi's artisanal production facility. Only 7-8 bottles are produced a year; the Mayor noted that the Queen of England was a recipient in 2008!*

## **1. Apologies for Absence**

As of 25 October, 57 members had written to the General Secretariat to apologize for their absence from the meeting (Enclosure 1). Fellows were reminded that it is helpful for the General Secretariat to receive regrets prior to 15 September of each year, the same deadline as event registration.

## **2. Adoption of the Minutes of the 2013 Council of Fellows**

The minutes of the Council of Fellows Meeting held on 27 October 2012 in Carpi were formally adopted by unanimous vote. All Council of Fellows minutes and enclosures dating back to 2001 are available for consultation in the member online dropbox:

<https://www.dropbox.com/sh/o6dk8noc7gonqqi/AACfjmn4o8RkBHO5UwJiJYha?dl=0>

### 3. Mayor's Welcome and Medal Ceremony

The meeting proceeded with the traditional medal ceremony. 13 members, representing 9 counties and 4 continents, who had not previously been to Carpi were presented with their silver Ramazzini medals by the President, Secretary General and Mayor as follows:

1. Baur, Xaver (Germany)
2. Chen, Jia (USA/China)
3. Duffy, Richard (USA)
4. Jarosinska, Dorota (Poland)
5. Jeebhay, Mohamed (South Africa)
6. Jensen, Tina (Denmark)
7. Kovats, Sari (UK)
8. Nguyen Bich, Diep (Vietnam)
9. Nowak, Dennis (Germany)
10. Rampal, Krishna (Malaysia)
11. Ritz, Beate (USA)
12. Von Braun, Margrit (USA)
13. Wright, Robert (USA)

### 4. President's Report

#### 4.1 Obituaries

##### **Dr. Simon Pickvance (U.K.), 23 November 2012**

The Collegium Ramazzini was made aware of the significant contribution to public health of Dr. Simon Pickvance from the United Kingdom in early November 2012. At the time Dr. Pickvance was already gravely ill with mesothelioma a work-related exposure to asbestos from three decades earlier. The Executive Council of the Collegium Ramazzini voted to elect Dr. Pickvance a special Emeritus Fellow and, through Fellow Andrew Watterson, delivered a letter and Ramazzini medal to Simon shortly before his death.

In 1972 Simon graduated in natural sciences from Cambridge University. He started a PhD in molecular biology with the Nobel laureate Sydney Brenner but became disenchanted, joining the Radical Science Journal collective and becoming active in the British Society for Social Responsibility in Science. His life was changed by a trip to China, then under the Cultural Revolution, where he was inspired by "barefoot doctor" healthcare.

On returning, he joined a migration of Cambridge radicals to Sheffield, training as a bricklayer and working in a building co-operative, while helping develop an occupational health service based on listening to people in working men's clubs and GPs' waiting rooms. Supported by other radical scientists, trade union representatives and sympathetic GPs, the initiative attracted official funding (never secure), leading to the creation of the Sheffield Occupational Health Advisory Service, a model copied elsewhere.

The service has tackled numerous workplace diseases such as occupational asthma, obstructive lung diseases, hard metal disease and various cancers, and its shopfloor knowledge often challenges the official health and safety and occupational medicine establishments. It undertakes research, campaigning and individual casework, leading to the identification of hazards, changes in workplace practices and compensation for workers.

Simon became part of a worldwide community of activists and was unfailingly generous with his expertise. His work was recognized by national and international awards, but he was a quiet man and did not seek rewards.

Two factors fashioned Simon's approach – his experience on the tools as a jobbing bricklayer and a respect for the greatly under-estimated knowledge held by working class men and women who have faced and challenged hazards in the workplace.

Simon continued working until the weeks before his death, his last two years concentrating on occupational bladder cancer. This was an interest that long preceded his diagnosis, and came out of his interviews in surgeries. The research, which is ongoing, had already established official estimates of work-related bladder cancer overlook most of the causes and many of the at risk occupations.

We received the following note from Simon's wife:

*Thank you very much for your letter of 6 November 2012.*

*I am Simon's widow – I imagine you will have heard that Simon died on 23 November.*

*During his life Simon sought neither fame nor awards, but I have to say that his election as Emeritus Fellow of the Collegium Ramazzini really touched him and brought him great satisfaction. At the end of his life it gave him strength. He wanted to thank you himself, but unfortunately this proved not to be possible. I am therefore thanking you sincerely on his behalf. Dr. Mandy Gamsu*

### **Dr. István Ember (Hungary), 1 June 2013**

This summer the Collegium lost one of its most active Fellows, Dr. István Ember from Hungary. Many of you will remember that Istvan organized a Collegium Ramazzini conference at his university in Pécs and brought a team of junior colleagues with him to Carpi both years of his short membership in the Collegium Ramazzini. By way of remembering Istvan, the President shared a letter, unabridged, that we received from one of these young colleagues who attended Ramazzini Days in 2011 and 2012 – you will quickly note in her words how important the Collegium Ramazzini was to Istvan.

*We share the woeful loss of Professor István Ember, member of Collegium Ramazzini and head of our Public Health Institute in the University of Pécs, Hungary. He passed away on June 1, at his age of 61.*

*Professor István Ember was born in 1952 in Debrecen, Hungary. He completed his studies at the University of Medicine in Debrecen with summa cum laude certification in general medicine. He achieved candidate's degree in medical sciences in 1989 and PhD in 1994. In 2003 he was named Doctor of the Hungarian Academy of Sciences.*

*He gained specialization in Laboratory Investigation in 1981, in Laboratory Investigation of Hygiene and Epidemiology 1989, Public Health and Preventive Medicine 2003 and Occupational Medicine 2008.*

*Between 1977 and 1992 he worked in the Department of Hygiene and Epidemiology in the University of Debrecen as volunteer, assistant lecturer and professor assistant. In 1992 he became the head of the Public Health Institute of University of Pécs where he was elected to serve as Vice Rector for Education between 1995-1997. Professor Ember strongly focused his activity on the field of the education of public health, epidemiology and preventive medicine and conducted the teaching of his institute's graduate and postgraduate university programmes and the postgraduate trainings for the medical officers. He was a member of the vocational educational committee and the leader of the Transdanubian vocational gremium for Public Health, Preventive Medicine and Hygiene. He established two PhD Programmes at the University of Pécs and the University of Marosvásárhely (Tirgu-Mures), where he mentored numerous PhD graduates. He continuously encouraged the support of Transylvanian Hungarian minority in many ways. He organized regularly bilateral conferences and frame budget proposals to strengthen the scientific collaboration between the mother country and Transylvania. Professor Ember regarded this activity as one of his major missions.*

*Professor Ember was a member of over 30 national and international scientific societies; he was chairman of the Hungarian Epidemiology Society and was founding member or member of the board of trustees in several scholarships and foundations. He was in the editorial board of numerous national and international scientific journals and he was the founding editor in chief of Hungarian Epidemiology and Journal of Proactive Medicine. Professor Ember edited and authored over 15 books and book chapters, out of which Medical Public Health is so comprehensive that it was accepted as the official educational textbook in two medical universities in Hungary, both in their graduate and postgraduate programmes.*

*In 2011, the Collegium Ramazzini, an internationally highly rated society of environmental and occupational health, elected him as a member. In the same year he organized a satellite meeting for the Ramazzini Collegium in Pécs University, for which activity he was honoured with the Ramazzini medal.*

*His special fields of interest were environmental and occupational carcinogenesis and prevention, molecular epidemiology of cancer, historical and geographical epidemiology and primary prevention of cancer. In Hungary, Professor Ember was the first to introduce molecular epidemiology approach into the field of public health. He developed his institute to be a center of molecular technology based cancer research and prevention.*

*Professor Ember was unique in so many interesting ways: besides being a leader, teacher, researcher and colleague he had outstanding literacy, especially in history, he also participated in a round table talk entitled National Visit, which programme was broadcasted on the Hungarian public television in series and was discussing the interconnections of history and medicine in high scientific quality. He loved nature and travelling. Personally he was extraordinarily open and utterly selfless. He restlessly worked for his Institute, Faculty, and University with the consciousness of responsibility to the Hungarian nation and to public health.*

#### 4.2 Membership

President Landrigan reported that the Executive Council voted unanimously to award Emeritus status to 7 Fellows. Emeritus status is not automatic but is instead reserved for Fellows who have made significant contributions to the organization. The new Emeritus Fellows are as follows:

1. Aaron Blair (USA)
2. David Groth (USA)
3. David Hoel (USA)
4. Kaye Kilburn (USA)
5. Ron Melnick (USA)
6. David Ozonoff (USA)
7. Jorma Rantanen (Finland)

Following the election of these 7 Emeritus Fellows, the total number of active Fellows was 167.

The President then reported election of the new Fellows whose candidacies had been carefully considered by the Executive Council. The full list of nominations for 2013, including candidates who were deferred in 2012 and 2011, is included as Enclosure 2.

The newly elected Fellows are listed below, 5 women and 2 men, hailing from Armenia, Japan, South Korea, and United States

1. Caldwell, Jane C., PhD , USA (female, d.o.b. 1959)
2. Eskenazi, Brenda, PhD, USA (female, d.o.b. 1949)
3. Kim, Rok Ho, MD PhD, South Korea (male, d.o.b 1958)
4. Kishi, Reiko, MD, PhD, MPH, Japan (female, d.o.b. 1950)
5. Lipscomb, Jane , PhD, RN, FAAN, USA (female, d.o.b. 1954)
6. Petrosyan, Varduhi, PhD, MSC, Armenia (female, d.o.b. 1970)
7. Robson, Mark Gregory, BS, MS, PhD, MPH, DRPH , FAAAS, ATS, USA (male, d.o.b 1955)
8. Rogers, Bonnie ME, MPH, DPH, USA (female, d.o.b. 1946)

The full membership roster and mailing list would be updated with new members and with any changes indicated by members during Ramazzini Days (Enclosure 3).

#### 4.3 Election of Officers

The Collegium Ramazzini used a web-based voting system called “Election Buddy” for the first time in. 93 out of 174 Fellows voted in the election, compared with 66 voters in the previous paper-based election. The results of the election are as follows:

- Jim Melius was elected Treasurer.
- The three candidates for Councillor who received the highest number of votes were Melissa McDiarmid, Fiorella Belpoggi and Henry Anderson.
- The fourth highest, who will complete the remaining two years of the mandate of Jim Melius was Ludwine Casteleyn.

The President thanked all candidates and recognized outgoing Treasurer Nachman Brautbar and outgoing Councillor Philippe Grandjean for their years of service on the Executive Council. The membership joined Landrigan in thanking Brautbar Grandjean with a round of applause.

The President then reminded Fellows of the calendar for future elections, noting that no offices would be up for election in 2014. Offices will become vacant as follows:

- President (2016)
- Secretary General (2015)
- Treasurer (2017)
- Councillor (2015 – Casteleyn, Froneberg, Van Damme)
- Councillor (2017 – Anderson, Belpoggi, McDiarmid)

#### **5. Treasurer’s Report**

Newly-elected Treasurer Jim Melius presented the Ramazzini Days event budget and the 2014 operating budget for the organization (Enclosure 4).

He reviewed the budget for Ramazzini Days, by far the largest expense of the organization. He noted that meeting expenses include direct payment of vendors and Kathryn Knowles’ consulting time. They do not include staff time from the Ramazzini Institute nor the in-kind contributions from the Town of Carpi such as meeting space. The total expenditure in 2102 was roughly 35K (euro). Income was comprised of 15K euro from registrations with additional funding from the European Environment Agency (5K euro) and the Oak foundation (25K euro), allowing the Collegium to run a surplus on the meeting in 2012 .

The estimated expenditures for 2013 are about 40K euro. More funds were collected in registration fees this year (25K euro) with carry over funding from the previous year of 5K euro. Nevertheless, it is estimated that the meeting will run a deficit as indicated.

It costs about 425 euro/attendee to put on the Ramazzini Days meeting. It will therefore be necessary to raise the registration fees in 2014 in order to get closer to a break-even point. Use of the cash carry over from last year’s operating budget (approximately 7,500 USD) means that the Collegium will deplete its cash assets.

Melius shared that his goal is to get 100 Fellows to pay their dues next year, therefore collecting 15K USD in dues. He noted that some Fellows have provided donations at the time of registration, but these totals only about 2500 USD. He said it will be necessary to raise at least 10K USD in outside support for the 2014 edition of Ramazzini Days. Considering the increase in registration fees we should be able to raise at least 36K USD.

In terms of fixed costs it is necessary to pay an accountant for reporting in order to maintain the 5013C non-profit status in the USA. Melius also notes his intention to pay resources back into the restricted fund, possibly in the amount of 10K USD. Melius would also like to be able to set aside 5K USD in travel support funds, however this figure will depend on the income collected over the year. In closing, Melius noted that

he will be able to diminish the administrative costs associated with the running of the Treasury because he has some institutional support for bookkeeping etc.

Knowles intervened to address two questions that are raised annually: the number of Fellows paying conference registration fees and the number of Fellows paying membership dues. She reported that the conference registration fee is mandatory and is pleased to report that for the first time close to 100% of attendees had settled up prior to arrival in Carpi. Knowles regrets that she does not have the same good news regarding payment of annual dues as only 60 Fellows (of 174 members) paid their fees to date. She reiterated Jim's goal of getting 100 members to pay their dues prior to the 2014 meeting.

Melius noted that people who attend the meeting are usually the ones who pay dues. No need to look at each other to guess who paid and who did not!

Ellen Silbergeld appreciates the clarity of the presentation and thanked Melius. She believes it is intolerable that so few members pay their membership dues and notes that it will be impossible to solicit foundation support if the organization's cannot demonstrate contributions from its own membership. She notes that we have discussed this for many years and is very concerned that the Collegium has been using its savings to support operational expenses.

Landrigan noted that each year the Executive Council reviews the membership list and, following a warning letter, removes members who have not attended the meeting or paid dues in 5+ years.

Daniel Teitelbaum notes that, as a former Treasurer, he has great sympathy for both the outgoing and incoming treasurers. He noted in more dues were collected as a percentage of membership in the past. He suggests that one reason is because the Treasurer's office used to personally call each member. He feels that after one year of arrears members should be moved to "inactive". After two years of inactive status he suggests that Fellows should be then removed from the rosters. He echoed Silbergeld's point about the difficulty of raising external funds if one's own house is not in order. Teitelbaum recalls that the only travel expenses he paid were those of Fellows who had been authorized by the Executive Council to have receive assistance. He also notes that we have not done a good job at asking members to can make contributions to do so. He feels that most "first world" members can afford a 200 USD fee in membership dues. He believes it was an error to reduce the fees to 150 USD. He feels that the burden for soliciting members should not fall exclusively on the Treasurer and suggests that the President should be signing the solicitation letters as well.

Nachman Brautbar agreed with Teitelbaum. He recalls that when he took over the Treasury he oversaw a calling and emailing campaign to collect arrears. He also remembers being told indirectly to not get into fights. Brautbar supports the position that if you do not pay you are out. He also supports the proposal for increasing the registration fee.

Arthur Frank congratulated Melius on the clarity and transparency of the event and operational budgets. He recommends the appointment of a finance committee to assist the Treasurer. Frank notes that this is not the first year funds have been removed from the restricted fund is pleased that there are plans to replenish the resources. He applauded the one-year budget and encouraged Melius to also think about a medium-long term plan. He would like to put something formal into the bylaws about defining what it means to be a member in good standing.

Melius responded that the Executive Council has appointed a finance committee chaired by Henry Anderson to assist the Treasurer.

Paul Lioy is distressed that over 100 members are in arrears and supports Teitlebaum's suggestion about inactive status. He also agrees with Silbergeld regarding the difficulty of soliciting foundations under the current condition. He offered his support.

Jennifer Sass also agrees with the idea to establish of a procedure for inactive status. She suggests that the Collegium also survey members about why they are not paying dues and/or note why they are not attending meetings. She pointed out that there are many reasons why people do not attend and that this should also be

taken into consideration when nominating and electing fellows. For example, Sass has spoken with some government employees are reluctant to come to Collegium meetings for political reasons during a time of great scrutiny.

Melius agreed with Sass and confirmed that he will collect this information when soliciting fees.

Christine Oliver suggested that dues be reconfigured on a sliding scale. She cited the fees of other professional societies like the American Thoracic Society and relayed dues figures ranging from 300-500 USD. She underlined that 150 USD is really a very low membership fee.

Aleksandra Fucic posed the hypothesis that Fellows may not feel that they are getting value out of their membership. She suggested having a password-protected website to provide incentives for Fellows to pay dues. Only members in good standing would be able to access the additional information.

Nicholas Ashford asked if the Collegium Ramazini had every considered going to a biannual meeting.

The President responded that it has been considered several times. He said that this is an organization that translates science into policy. Biannual meetings do not allow the organization to stay in front of the curve. The organization must balance the question of expense with that of fulfilling its mission.

Beate Ritz suggested using technology such a webinars to stay connected. She says she opposes the idea of locking up any information, on the contrary she believes the Collegium should give it away for free.

Colin Sosklone asked about extending the time of the meeting by at least a day. The President responded that this is being considered for 2015, the ten-year interval in which the Collegium focuses its meeting on the topic of "Living in a Chemical World". Beginning in 2014 the Collegium will experiment with holding the Council of Fellows business meeting on Friday in order to dedicate all of Saturday to scientific sessions.

Martin Cherniak says that every year his level of tolerability seems to go up and does not feel as enraged. In terms of attendance he feels the strongest indicator of coming is that one has attended the year before or two years before. He agrees that the survey suggested by Jennifer Sass is important but not organization-saving. He recognized that the budget is very small but that we also need to recognize how much time is dedicated to the organization and consider establishing a way for people to pay their dues with in-kind contributions. Cherniak is also interested in identifying a "deep pocket" who could make a transformational gift.

Landrigan seconds the notion of seeking out a major donor and is available to speak with any prospects. He pointed out the success of receiving contributions from EEA and the Oak Foundation. He announced the intention of the organization to undertake more active fundraising.

Daniel Teitelbaum issued a challenge to Melius, offering to match funds for any arrears collected from Fellows who had not paid in 3 years. The membership applauded this offer.

*--Member photograph followed by coffee break, courtyard--*



## 6. Secretary General's Report

### 6.1 Activity of the Collegium

Secretary General Morando Soffritti reported that 2013 had been an active year for the Collegium Ramazzini, especially with regard to advocacy in Europe. He invited Fellows Ludwine Casteleyn and Philippe Grandjean to update the membership on the activity of the **Chemicals Control Committee**.

The Chemical Controls Committee was initiated in 2010 as a follow up of the precautionary principle group. Based on a first general text on chemical control, a draft 'CR Statement on chemicals control - A Call for Action to Protect Human Health' was discussed at the CR meeting in October 2012. Comments were included in an adapted and shortened version issued in March 2013. External experts in communication advised to look for more focus in terms of geography and in terms of content, e.g. to address 3 separate policy audiences: European Union (EU) concerning the Endocrine Disrupting Chemicals (EDC) strategy, US with the Toxic Substances Control Act (TCSA) reform, and global chemical and health – Strategic Approach to International Chemicals Management (SAICM).

The first window of opportunity was the revision of EDC strategy by the EU with the development of criteria for identifying and assessing EDCs and the decision on whether a threshold level for effects can be determined for EDCs or not. In June 2013 the Collegium Ramazzini statement was sent to European Commission (EC) President Barroso and to Professor Anne Glover, Chief Scientific Advisor to Barroso, and uploaded on the website of CR ([Enclosure 5](#)).

The recommendation focuses basically on improving testing protocols and testing requirements, including academic research as a basis for risk assessment, treating EDCs under REACH as substances of very high concern (no safe threshold), applying strict cut-off criteria based on hazard assessment, and reducing and monitoring exposure. In Early July the statement was cited in an editorial in the Lancet. [See [www.thelancet.com](http://www.thelancet.com) Vol 381 June 29, 2013 - p.2223, "*Recently the Collegium Ramazzini and the European Environment Agency recommended a precautionary approach for exposure to endocrine disrupting chemicals...*"]

In August 2013 a group of editors responsible for 14 of the scientific journals that cover research on adverse effects of chemicals released a joint statement that any regulatory action to control industrial chemicals that affect hormone functions in the body would be premature and unjustified. A September 2013 report in Environmental Health News showed that 17 of the 18 signatories of the letter have conflicts of interest, such as receiving money from the chemical industry:

<http://www.environmentalhealthnews.org/ehs/news/2013/eu-conflict>

Based on reviews on behalf of the European Commission and the World Health Organization, and on other research data, other leading scientists stressed that, on the contrary, public health attention was needed and, possibly, regulatory action:

<http://www.sciencedirect.com/science/article/pii/S0009279713001610>

[http://www.altex.ch/resources/open\\_letter.pdf](http://www.altex.ch/resources/open_letter.pdf)

As a follow-up to these messages, Professor Ann Glover called for an informal meeting with representatives from the parties (Dekant and Dietrich versus Bergman and CR) to discuss the scientific evidence and to identify where a scientific consensus could be found:

<http://www.nature.com/news/journal-editors-trade-blows-over-toxicology-1.13787>

Due to earlier commitments, neither Casteleyn nor Grandjean were unable to attend the meeting. Anna-Maria Andersson kindly accepted to attend for CR (Andersson is a close associate of Niels Skakkebaek, now retired and father of the "estrogen hypothesis". She has a center grant from the Danish government for EDC research, and she was the main author of the EU input to the WTO on the hormone-beef controversy). The minutes of the meeting were posted on the CSA website ([Enclosure 6](#)): [file:///C:/Users/kknowles/Desktop/minutes\\_endocrine\\_disruptors\\_meeting\\_241013\\_final.pdf](file:///C:/Users/kknowles/Desktop/minutes_endocrine_disruptors_meeting_241013_final.pdf)

Grandjean underlined just how great of an impact the Collegium Ramazzini can have in the policy sphere and noted that timing is of the utmost importance.

Nicholas Ashford stated that “17 heads should roll”. The Collegium Ramazzini won the battle but the war is getting these corrupt editors out.

Silbergeld shared the mechanism for doing so. There is a Committee on Publication Ethics (COPE) in London that tries to get journal editors to join. There is nothing inherent about conflict of interest and publishing. But there is an organization that has the power to give a stamp of approval is important. See <http://publicationethics.org/>

Ana Soto shared that she read in a French newspaper that due to this debate the Commission is buying time and asked is this is indeed the case?

Grandjean responded that the Commission has informed the parliament that they need a year to renew the REACH legislation. Grandjean believes this is reasonable, we need to time to document all of the effects of EDCs. The Collegium needs to follow this closely. He anticipated that there may be a need for a second statement in six months.

Fiorella Belpoggi complimented the authors of the statement. She says she has personally seen a change in the attitudes of policy makers. In September she was invited to the European Parliament to share suggestions about how to improve the OECD guidelines. On this occasion she met with representatives from DG Environment and two MEPs from Greece and Slovakia. They have asked Fiorella to write a draft of how these guidelines should change. The Ramazzini Institute and Mt. Sinai School of Medicine (Fellow Jia Chen) will be working together on this project.

Morando Soffritti noted that the EDC case mirrors what happened following the publication of the Ramazzini Institute’s data on aspartame. First rebuttals were published, then the conflicts of interest of European Food Safety Authority experts were revealed, then industry reacted. Now, eight years later, the tides are turning. The discussion on EDCs shows how important it is to be a part of the debate in the European Commission.

Xaver Baur fears that this is only the tip of the iceberg. The political process mirrors many other experiences, including asbestos and other carcinogenic agents.

Daniel Teitelbaum recalls a similar story with the hematology journal Blood in which an industry deposition had been published without a conflict of interest statement. Teitleman and Brautbar challenged it in a letter to the editor.

Arthur Frank shared that several Fellows recently responded to a statement in an Australian journal that had made some outrageous statements about asbestos. When called out by a letter it turned out that a reviewer and editor of the journal had actually been involved in influencing the author to include the statement. Aspartame 8 years, Asbestos 108 years, Benzene since 1894. This reminds us of the importance of the Collegium Ramazzini and remaining vigilant.

Soffritti then invited Denny Dobbin to report on the **two-day meeting held on 22-23 April 2013 at the American University of Armenia (AUA) on mining and construction-related environmental and occupational health in transition economies.**

The AUA School of Public Health and the AUA Acopian Center for the Environment in cooperation with the Collegium Ramazzini, organized the symposium titled “Emerging Issues in Environmental and Occupational Health: Mining and Construction in Transition Economies.” The symposium aimed to improve the understanding of how evidence-based scientific findings can be applied strategically to protect workers’ and community health.

The symposium covered such important topics as: the World Health Organization's (WHO) resolution on workers' health and plan of action in the WHO European Region; human carcinogens, especially those related to mining; preventing mining-related illness in miners and the community; environmental and work-related cancer, and preventing work-related illnesses in construction workers.

The audience included experts from the Ministries of Health and Environmental Protection and local government offices, a broad spectrum of occupational and environmental health scientists and professionals working in universities and non-governmental organizations, faculty, students and researchers from AUA and other universities, representatives of private industry and civil activist groups. Participating Fellows included Crespi, Dobbin, Englund, Langard, Mehlman, Natali, Nowak, Petrosyan, Rice, Soffritti, Straif and von Braun.

The symposium was possible thanks to the following organizations for sponsorship and in-kind support: Collegium Ramazzini, American University of Armenia, World Health Organization, USA National Institute of Environmental Health Sciences, TerraGraphics International Foundation, Blacksmith Institute, and Counterpart International. The Civil Society/Local Government Support (CSLGS) Program, a Counterpart International project in partnership with and generously supported by the United States Agency for International Development (USAID), supported participation of 33 participants from different marzes of Armenia, including representatives of local government offices and NGOs.

The symposium was streamed live online at <http://civilnet.am>. All the symposium presentations and videos are available at <http://coh2013.aua.am>

Dobbin concluded by sharing the idea of having a committee to develop a regional meetings emerged from the Armenia experience. The committee would like to next hold a meeting in Bangladesh, in particular to try to expand the themes from fire safety to more general occupational health and safety.

## 6.2 Institutional Collaborations

Colin Soskolne provided an update from the **Joint Policy Committee of the Societies of Epidemiology** (JPC-SE representative). The JPC-SE was formed as a consequence of a meeting of the leaders of the epidemiology societies at the Second North American Congress of Epidemiology held in Seattle in 2006. Today, the JPC-SE comprises 14 member societies that includes not only North American, but also multiple international societies of epidemiology. The website for information about the JPC-SE is at [www.jpc-se.org](http://www.jpc-se.org).

It was in October, 2012 that the Collegium's Executive Council supported the affiliation of the Collegium with the JPC-SE. Given the Collegium's role in policy and the JPC-SE's role in informing policy, the Collegium's Fellows were supportive of membership in the JPC-SE. From 2007 until recently, Colin Soskolne, as President of the Canadian Society for Epidemiology and Biostatistics (CSEB) represented the CSEB on the JPC-SE. Colin's term on the Executive of the CSEB concluded at the end of June, 2013. With that term ending, Colin was able to take on the role of representing the Collegium Ramazzini after receiving his formal appointment to that role from the Collegium's Secretariat, dated July 25, 2013.

Sosklone invited any Fellow who would be able to serve as a co-representative should please step forward and inform the General Secretariat. The JPC-SE prefers to have at least one back-up should the lead representative member be unavailable for its scheduled monthly conference calls, which each last about an hour.

Sosklone then shared some highlights from the past year. Since its launch in July 2012, the JPC-SE Position Statement on Asbestos has received widespread endorsements and publicity. The Collegium Ramazzini was one of the first organizations outside the JPC-SE itself to endorse the Statement. He is delighted that the Statement is having a broad international impact, being as it represents the first time that epidemiologists have come together in a unified assessment that all forms of asbestos cause harm and should be banned. This assessment places a barrier before defendant lawyers who attempt to claim that there is disagreement among epidemiologists as to the harms from all forms of asbestos, especially chrysotile; they have tried to do this in an attempt to justify delays and to play on division. The defendant lawyers in some US litigation have

demanding access to all e-mails, prior drafts, and the like, of the Position Statement. The JPC-SE considered these requests. The JPC-SE speculates that the reasons for this level of adversarial attention could be two-fold: to intimidate individual members of the member society boards who voted to support the Statement through its several iterations, as well as the JPC-SE representatives, and to try to limit its use. These recent experiences by the JPC-SE have resulted in the JPC-SE alerting its member societies of a need to consider the status of their own society records, with a JPC-SE recommendation that they should be examined and developed in the future so as to be transparent and publicly accessible. This decision has implications for website management and the like for the JPC-SE and each of its member societies, including the Collegium.

A major ongoing administrative project of the JPC-SE is the process of development of By-laws and disclosure policies. It is anticipated that the latter will help inform development of similar policies for each society. This By-laws document is still being developed and we expect that it will soon be made available as a draft for review and input by the full boards/councils governing each of its member societies. An important article in the draft allows, thus far, for abstentions by JPC-SE member societies if they, for any reason, would rather not participate in the development of a Position Statement on a particular substance. This article is also being designed to help individual board/council members whose employing agency could take exception to any role they might play in the development of a Policy Statement about which the employing agency may be sensitive. The implication of the latter concern relates to protecting the jobs of individual board/council members that could be put in jeopardy if they were seen to be participating in policy matters that go counter to their employing agency's narrow interests.

A further item of major significance on which the JPC-SE is working is that of its name. The proposal in the draft By-laws is to change the name of the JPC-SE to better reflect the very international make-up of the Committee. Hence, the proposal is to insert the word "International" as follows: "International Joint Policy Committee of the Societies of Epidemiology" (IJPC-SE). The Collegium Ramazzini unanimously approved this change.

During the International Society for Environmental Epidemiology (ISEE) conference in Basel, Switzerland, in August 2013, its Ethics and Philosophy Committee resolved to work with its Policy Committee in developing a Position Statement on lead exposure. The motivation stems from USA current interest in changing exposure limits that would serve to harm public health. Collegium Ramazzini Fellow Bruce Lanphear, has become part of that working group and has shared the Collegium's lead statement from 2008 with Frank Rosenthal who is leading the ISEE initiative. The hope is that, once the ISEE has completed this work, the JPC-SE would want to endorse it.

Finally, of note is that the JPC-SE has set as a method for engaging in developing new Position Statements that one of the JPC-SE representatives agrees to serve as the shepherd or champion; also, outside experts can be called upon to assist in the process after the JPC-SE has approved their participation.

Massimo Crespi asked if the JPC-SE is considering how cancer registries work together across five continents? This could provide an interesting basis for collaboration. Sosklone said that JPC-SE would be pleased to explore this possibility.

Daniel Teitelbaum asked how the US can issue subpoenas for documents outside of the US?

Sosklone responded that the bylaws will be reviewed by a team of international lawyers to address these questions.

Ana Soto commended Sosklone for his representation of the Collegium Ramazzini. She asked if the JPC-SE has a statement on ethics that she could review. She shared that she was challenged by someone at the PPTOX meeting who said that as a government employee paid by tax payers she had a conflict of interest. She asked if there are any existing guidelines that address this.

Sosklone suggested that she review the ethics guidelines produced by the The International Society for Environmental Epidemiology (ISEE): <http://www.iseepi.org/>

Soffritti then invited Landigran introduce a proposal for the Collegium Ramazzini to join the **Network for Effective Collaboration in Children's Environmental Health**.

The WHO has formed a worldwide network in Children's Environmental Health. There are a total of 6 or 7 centers involved, including Mt. Sinai Medical School, the Chulaborn Institute in Thailand, the US NIEHS and others. Fellow Peter Sly of Australia serves as the Secretary of this group has invited the Collegium to become a partner organization.

**Objectives:**

1. To reduce morbidity and mortality of children by identifying and controlling environmental risks.
2. To reduce the burden of chronic non-communicable disease throughout life by understanding the contribution of environmental exposures in early life and developing ways to reduce these.

**Aims:**

1. To bring together WHO Collaborating Centres and new partners in Children's Environmental Health to enhance collaboration in the area.
2. To assist the Public Health and Environment Department of WHO to address their priorities in Children's Environmental Health.
3. To set and implement a research agenda in Children's Environmental Health
4. To build capacity in Children's Environmental Health.

**Implementation:**

1. Develop a Framework of Action for Children's Health and the Environment to guide activities of the network.
2. Transition activities in Children's Environmental Health from an exposure-based focus to a health effects-based focus.
3. Establish collaboration between the network and groups within WHO to ensure a focus on Children's Environmental Health to existing programs.
4. Establish collaboration between the network and UN agencies and organizations to introduce a focus on Children's Environmental Health to existing programs and seek the expertise of international actors in related fields.
5. Enhance communication between the network by developing and maintaining a specific web-based presence for the network.
6. Increase awareness of Children's Environmental Health issues through international conferences and other education-related activities.

Landigran explained that the expectation is that the Collegium Ramazzini will participate in any annual meetings and the drafting of documents in the field of children's environmental health. Many Fellows are already involved in the network as individuals so he believes there will not be an additional burden of work.

Teitelbaum stated that he is not in favor of any collaboration that strengthens the relationship with the Thai regime, due to how the regime handles worker's rights.

Landigran responded that he does not think this is a relevant question; this is a proposal to join a network of the World Health organization.

The President asked for a motion to call the question. The Collegium Ramazzini unanimously approved to join the network. Landigran said he will inform Fellow Peter Sly of this decision.

The President then offered the suggestion that a committee be formed to address issues in children's health.

Mary Wolfe added that this committee could address issues in child labor.

Silbergeld shared that she is concerned about the focus of the Collegium shifting away from its roots in occupational health.

Chris De Rosa supports the idea of endorsing children's environmental health as a priority topic for the Collegium because the issues affecting children are absolutely relevant to the issues at the core of the Collegium's interest.

The President responded to Silbergeld saying that focusing on vulnerable populations is in line with the Collegium's origins.

Melissa McDiarmid is concerned about the mechanics of forming a break-out group that is interested in children's health. She feels these issues are transversal and apply to the whole body.

Soto offered an intermediate position. She thinks that groups can be formed around issues rather than form a standing committee on children's environmental health.

Cherniak followed up on Silbergeld's point. He notes the growing erosion of advocacy for workers and workers' health in the US. He'd like to see a return to this focus.

### 6.3 Future activities

Knowles reported that Fellow Paul Blanc had requested the Collegium Ramazzini's endorsement of Occupational and Environmental Factors in Infectious Disease: Updates in Occupational Health meeting at UCSF, 6-8 March 2014.

Knowles discussed **endorsement of external meetings** and the use of the Collegium Ramazzini logo. She clarified the difference between sponsorship (financial) and endorsement (use of name, logo). In order for a meeting to be endorsed by the Collegium Ramazzini two conditions must be met: 1) a Fellow must be involved in the planning of the scientific program; and 2) at least one Fellow must be included as a speaker on the program. Requests for endorsement should be made by email to the General Secretariat.

Daniel Teitelbaum suggested that institutions that receive the endorsement of the Collegium Ramazzini offer a student rate to doctoral students of Fellows.

Soffritti then asked Landrigan to introduce a proposal to hold a **high-profile regional conference on environmental hazards in SE Asia and the Western pacific**. The goal of the conference is to focus on global issues that have particular specificity in the region such as asbestos and pesticides. The symposium will be hosted by the Chulabhorn Institute in Thailand; the goal is to organize the meeting in the coming year.

Landrigan underlined the importance of regional symposia of this nature recalling a delegation led by Selikoff to Japan, at the time a major importer and user of asbestos. This visit was followed by years of dedicated work by late Fellow Yasunosuke Suzuki who spent most of his career at Mt. Sinai in the United States. Asbestos was eventually banned in Japan, it was an enormous triumph for public health.

The plan is to involve a group of non-monetary sponsors in the project including WHO Geneva, WHO Manila, WHO New Delhi, IARC, a number of WHO Collaborating Centers, the Blacksmith Institute and others. Landrigan, Lucchini and McDiarmid have begun preliminary discussions regarding the scientific program.

Henry Anderson asked if dates have been set. Landrigan replied that the scheduling is still to be defined.

Knut Ringen asked if the meeting will include occupational issues and if so, suggests involving the ILO and Special Commission on Prevention of the International Social Security Association. Landrigan agreed and asked Ringen to provide contacts.

Sass asked if the manufacture, in addition to the import, of pesticides will also be covered.

Soffritti remembered an episode in 1983 during the “storm of benzene”. Maltoni called Selikoff and said that they must do something. Based on that phone call the first Living in a Chemical World conference was born.

Jim Melius said that it will be important for workers’ advocates to be a part of the meeting.

The President called the question and the Collegium’s participation in the meeting was approved.

Soffritti next invited Melissa McDiarmid to deliver an update from the **Priority Topics Committee**.

Looking ahead to 2015, McDiarmid anticipated that the plan is to hold a longer meeting, possibly 3 full days. The committee is accepting proposals for up to four scientific sessions. The committee is also accepting proposals for thematic sessions in 2014. Interested session chairs should send a 1-page proposal to the committee with a session title and 4-5 potential speakers. She then reminded the body that the current financial situation means that we are unable to support travel expenses for speakers outside the Collegium Ramazzini.

Soffritti then asked Frank Mirer to present his proposal for **drafting a statement on Silica**.

Mirer shared that the US OSHA has a new proposal for the regulation of Silica. He believes it is important for the Collegium to weigh in and develop a response by mid-January. Specifically the issues to address are 1) the scientific quality of the supporting data and 2) the ethics of medical surveillance.

Jim Melius added that Fellows Anderson, Oliver, Melius and Mirer and Melius would be working on the Collegium Statement and invited others to join the effort.

## 6. Membership News and Views

Crespi would like to update cancer screening statement.

Ashford made an announcement about his new book *Technology, Globalization, and Sustainable Development: Transforming the Industrial State*.

Frank reported that he went to Mongolia this year to speak about asbestos thanks to a collaboration managed by Silbergeld. He also shared that several Collegium Fellows are teaching for TK Joshi in India this year including Castleman, Frank Rice and Ringen. Finally, he reported that the Asbestos Disease Awareness Organization (ADAO) bestowed the honor of their “Dr. Irving Selikoff Lifetime Achievement Award” on Frank and Richard Lemen this year; Fellow Ken Takahashi has been designated next year’s recipient.

Sosklone shared that the Russian study on Chrysotile asbestos with IARC’s oversight may be cancelled. Russian infiltration of IARC may very well be stopped, thanks to the work of Collegium Fellows and the contribution of Kathleen Rust who will be receiving a special award from the Collegium on Sunday.

Castelman remarked that the chief judge in the Eternit case in Italy, Giuseppe Casalbore died yesterday, 25 October. He is the judge who convicted Stephan Schmidheiny and Jean-Louis de Cartier de Marchienne, executives of corporations belonging to the Eternit Group of companies, for their roles in the contamination of sites in northern Italy. He also noted the movement to strip Schmidheiny of the honorary degree he had received from Yale University in 2006, ironically for being one of the one of the “world’s most environmentally conscious business leaders”.

Mirer shared that one of the things he did at OSHA was a comparison of data now available on the OSHA website. For example, a new list of priority exposure limits is now available. He encouraged those who are teaching in this area to refer to these webpages: <https://www.osha.gov/opengov/healthsamples.html>

De Rosa mentioned the issue of hydraulic fracking, its intensive use of water and sand and its possible association with seismic activity. For the past 2,5 years De Rosa has been briefing commissioners on the

chemicals that are being used in the fracking process. There is room for the Collegium's participation in this issue. For those interested in the topic, De Rosa recommends the new film produced by Matt Damon, *The Promised Land*.

Roberto Lucchini reported on the 2012 Brescia summer school, a 1-week course that received the Collegium's endorsement. The title was "Occupational and environmental determinants of disease: Multidisciplinary approach as a key for research and prevention". Lucchini plans to host the 4<sup>th</sup> edition in 2013 and will seek the Collegium's renewed endorsement.

Von Braun thanked Castleman for his work on asbestos substitutes that were used at the recent meeting in Armenia.

Teitelbaum congratulated Soffritti and Belpoggi on the EPA's endorsement of the Ramazzini Institute's studies and methodology. He also mentioned his own participation (producer/actor) in the documentary "Split a State" on fracking. The film won an Emmy.

Soffritti thanked Teitelbaum and recognized how many Fellows had supported this effort in recent years, especially newly-elected Fellow Jane Caldwell, author of the EPA endorsement.

Elihu Richter announced the forthcoming 7th International Conference on Children's Health, Environment and Safety to be held on 20-22 November 2013. Fellows Etzel, Finkelstein and new Fellow Brenda Eskenazi are involved.

## **7. Meeting/Journal Announcements**

Fellows are invited to share announcements regarding upcoming scientific meetings with the General Secretariat for posting on the Collegium website.

Kathryn Knowles highlighted an invitation from Fellow Aleksandra Fucic to publish Ramazzini Days presentations in the journal *Biomonitoring*.

The meeting was adjourned at 12:45.



**REGRETS RAMAZZINI DAYS 2013***updated 27.10.2013*

	LAST NAME	FIRST NAME	DATE	NOTES
1	ALBIN	MARIA	07/10/2013	
2	ANWAR	WAGIDA	01/09/2013	
3	AU	WILLIAM	12/09/2013	
4	BAILAR	JOHN	16/07/2013	
5	BERLIN	MATHS	15/09/2013	
6	BLANC	PAUL	11/09/2013	
7	CHRISTIANI	DAVID	03/10/2013	
8	CORRA	LILIAN	24/10/2013	
9	DEGLI ESPOSTI	DAVIDE	25/10/2013	
10	DONNELLY	THOMAS	19/09/2013	
11	EASTMOND	DAVID	11/09/2013	
12	EHRlich	RODNEY	12/09/2013	
13	ELLINGSEN	DAG	09/09/2013	
14	ENGLUND	ANDERS	11/09/2013	
15	ETZEL	RUTH A.	24/07/2013	
16	FINKELMAN	JACOBO	16/07/2013	
17	GEE	DAVID	05/10/2013	
18	GOCHFELD	MICHAEL	11/09/2013	
19	GREENBERG	MORRIS	16/07/2013	
20	HARARI	RAUL	11/09/2013	
21	HARDELL	LENNART	08/10/2013	
22	HARRISON	ROBERT	11/09/2013	
23	HAY	ALASTAIR	16/07/2013	
24	HOGSTEDT	CHRISTER	01/10/2013	
25	HOWARD	VYVYAN	16/07/2013+7/10/2013	
26	HUFF	JAMES	16/07/2013	
27	HUSGAFVEL-PURSIAINEN	KIRSTI	12/09/2013	
28	JACKSON	RICHARD	09/10/2013	
29	JOSHI	TUSHAR	11/09/2013	cancelled registration
30	KELSEY	KARL	11/09/2013	
31	LABORDE	AMALIA	11/09/2013	
32	LEMEN	RICHARD	23/09/2013	
33	MARKOWITZ	STEVEN	12/09/2013	
34	MCGLASHAN	NEIL	19/07/2013	
35	MEHLMAN	MYRON	30/09/2013	cancelled registration
36	MELNICK	RON	11/09/2013	
37	NEMERY DE BELLEVAUX	BENOIT	12/09/2013	
38	NGOWI	VERA	13/05/2013	
39	NUWAYHID	IMAN	13/09/2013	
40	OKUBO	TOSHITERU	31/07/2013	
41	OZONOFF	DAVID	11/09/2013	
42	POTT	FRIEDRICH	01/10/2013	
43	ROGAN	WALTER	07/10/2013	
44	ROSENMAN	KENNETH	19/08/2013	
45	ROSENSTOCK	LINDA	16/07/2013	
46	SLY	PETER	11/09/2013	
47	SMITH	MARTYN	29/07/2013	
48	STRAIF	KURT	12/09/2013	
49	SUK	BILL	14/10/2013	cancelled registration
50	TERRACINI	BENEDETTO	07/10/2013	
51	TOMPA	ANNA	17/07/2013	
52	TOREN	KJELL	16/07/2013	
53	VAINIO	HARRI	01/08/2013	
54	WAGNER	GREGORY	16/07/2013+28/09/2013	
55	WARDENBACH	PETER	09/09/2013	
56	WATTERSON	ANDREW	11/09/2013	
57	WHITE	ROBERTA	13/09/2013	

COLLEGIUM RAMAZZINI  
NOMINATIONS FOR MEMBERSHIP 2013-2012-2011

NEW NOMINATIONS PRESENTED IN 2013 (Valid through 2015)

**2013.1 CALDWELL, JANE C., PhD**

USA (Female; Personal Matters / Ex. 6)

*Office of Research and Development, National Center for Environmental Assessment, Washington Division, United States Environmental Protection Agency, USA*

Proposed by SOFFRITTI; Seconded by MEHLMAN

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**2013.2 ESKENAZI, BRENDA, PhD**

USA (FEMALE; Personal Matters / Ex. 6)

*Jennifer and Brian Maxwell Professor of Maternal and Child Health and Epidemiology; Chair of the Division of Community Health and Human Development, School of Public Health, University of California at Berkeley, USA*

Proposed by STAYNER; Seconded by KOGEVINAS

\*\*\*

**2013.3 KIM, ROK HO, MD PhD**

South Korea (Male; Personal Matters / Ex. 6)

*Team Leader, Environmental and Occupational Health, Suva, Fiji, WHO. Until 2012 Manager, Occupational Health, European Centre for Environment and Health, Bonn, Germany, WHO.*

Proposed by FRONEBERG; Seconded by KOGI, RANTANEN, TAKAHASHI, TAKALA

\*\*\*

**2013.4 PETROSYAN, VARDUHI, PhD, MSc**

Armenia (Female; Personal Matters / Ex. 6)

*Associate Dean of the American University of Armenia School of Public Health and Director of the Center for Health Services Research and Development, Armenia*

Proposed by DOBBIN; Seconded by SOFFRITTI

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**2013.5 ROBSON, MARK GREGORY, BS, MS, PhD, MPH, DrPH (hc), FAAAS, ATS**

USA (Male; Personal Matters / Ex. 6)

*Dean of Agricultural and Urban Programs, Professor and Extension Specialist in Entomology (Primary), Rutgers University-School of Environmental and Biological Sciences; Professor of Environmental and Occupational Health (Secondary), Rutgers University-School of Public Health, New Jersey, USA*

Proposed by LIOY; Seconded by GOCHFELD

\*\*\*

**2013.6 VINCETI, MARCO, MD, PhD**

Italy (Male; Personal Matters / Ex. 6)

*Associate Professor of Epidemiology and Hygiene, Department of Public Health Sciences, Medical School of Modena and Reggio Emilia University, Italy.*

Proposed by FRANCO; Seconded by RICHTER

\*\*\*

**2013.7 WEISS, STANLEY H., MD**

USA (Male; Personal Matters / Ex. 6)

*Temured Professor, Department of Preventive Medicine & Community Health, Rutgers, New Jersey Medical School, USA*

Proposed by SOSKOLNE, CASTELMAN, LEMEN; Seconded by FRANK

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**NOMINATIONS PRESENTED AND DEFERRED IN 2012 (Valid through 2014)**

**2012.1. GARG, SUNEELA, MBBS, MD**

India (Female, ☐ Personal Matters / Ex. 6)

*Professor of Community Medicine, Coordinator Post-Graduate Fellowship in HIV Medicine, Maulana Azad Medical College & Associated Hospitals; Head, Community Medicine, Faculty of Medical Sciences, Delhi University, New Delhi, India.*

Proposed by FRANK; Seconded by JOSHI

\*\*\*

**2012.1. KISHI, REIKO, MD, PHD, MPH**

Japan (Female, ☐ Personal Matters / Ex. 6)

*Director and Professor of Center for Environmental and Health Science, Hokkaido University, Japan*

Proposed by ETZEL; Seconded by YANO; HA

\*\*\*

**2012.3. LIPSCOMB, HESTER J., MPH, PHD**

USA (Female, ☐ Personal Matters / Ex. 6)

*Professor, Division of Occupational and Environmental Medicine, Department of Community and Family Medicine, Duke University, Durham, NC, USA.*

Proposed by SILBERGELD; Seconded by DEMENT

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**2012.4. LIPSCOMB, JANE A., PHD, RN, FAAN**

USA (Female, ☐ Personal Matters / Ex. 6)

*Tenured Professor, University of Maryland School of Nursing, Baltimore, MD, USA*

Proposed by DOBBIN; Seconded by LANDRIGAN

\*\*\*

**2012.5. ROGERS, BONNIE ME, MPH, DPH**

USA (Female, ☐ Personal Matters / Ex. 6)

*Director, North Carolina Occupational Safety and Health Education and Research Center; Director, Occupational Health Nursing Program and Nurse Administrator, Public Health Nursing, University of North Carolina School of Public Health, Chapel Hill, NC, USA.*

Proposed by RINGEN; Seconded by MCDIARMID

**NOMINATIONS PRESENTED AND DEFERRED IN 2011 (Valid through 2013)**

**2011.1. BEANE FREEMAN, LAURA, PhD**

USA (Female, Personal Matters / Ex. 6)

*Tenure Track Investigator, Occupational and Environmental Epidemiology Branch, Division of Cancer Epidemiology and Genetics, National Cancer Institute, Bethesda, MD, USA.*

Proposed by BLAIR; Seconded by RINGEN and STRAIF

\*\*\*

**2011.2. GROOPMAN, JOHN, PhD**

USA (Male, Personal Matters / Ex. 6)

*Anna M. Baetjer Professor of Environmental Health and Chair of the Department of Environmental Health Sciences, Johns Hopkins University Bloomberg School of Public Health (1993- ); Professor of Oncology and Associate Director of Cancer Center for Cancer Prevention and Control, Johns Hopkins School of Medicine and Sidney Kimmel Comprehensive Cancer Center (1994- ); Director, NIEHS Center in Urban Environmental Health, Johns Hopkins University (1996- ); Professor of Environmental Health Sciences, Johns Hopkins University, School of Hygiene and Public Health (1992- ), Baltimore, MD, USA.*

Proposed by SUK; Seconded by OZONOFF, BIRNBAUM

\*\*\*

**2011.3. MILLER, AUBREY K., MD, MPH**

USA (Male, Personal Matters / Ex. 6)

*Captain, US Public Health Service, Senior Medical Advisor Office of the Director, National Institute of Environmental Health Sciences, National Institutes of Health, USA.*

Proposed by DOBBIN; Seconded by BINGHAM, DEMENT, MIRER, RINGEN

\*\*\*

**2011.4. NAIDOO, RAJEN, MPH, PhD**

South Africa (Male, Personal Matters / Ex. 6)

*Associate Professor of Occupational Medicine, Centre of Occupational and Environmental Health Faculty of Medicine, University of Natal, South Africa.*

Proposed by LONDON; Seconded by MYERS, EHRLICH

\*\*\*

**2011.5. VIOLANTE, FRANCESCO S., MD**

Italy (Male, Personal Matters / Ex. 6)

*Professor of Occupational Medicine, University of Bologna, Italy.*

Proposed by CHRISTIANI; Seconded by LUCCHINI

\*\*\*

**2011.6. WAISSMANN, WILLIAM, MSC, DSC**

Brazil (Male, Personal Matters / Ex. 6)

*Researcher Oswaldo Cruz Foundation - FIOCRUZ (Brazilian Ministry of Health) and Professor of the Human Ecology, Sérgio Arouca National School of Public Health (ENSP), Rio de Janeiro, Brazil.*

Proposed by SILBERGELD; Seconded by FINKELMAN and CLAUDIO

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**FELLOWS ELECTED IN 2012 (13 total: 7 men, 6 women)**

1. ASSENNATO, GIORGIO, Italy (Male)
2. BAUR, XAVER, Germany (Male)
3. DEGLI ESPOSTI, DAVIDE, Italy (Male)
4. GUNDY, SAROLTA, Hungary (Female)
5. JAROSINSKA, DOROTA, Poland (Female)
6. NEIRA, MARIA P., Spain (Female)
7. NGUYIEN BICH, DIEP, Vietnam (Female)
8. NOVAK, DENIS, Germany (Male)
9. OCHIR, CHIMEDSUREN “CHIME”, Mongolia (Female)
10. RAMPAL, KRISHNA GOPAL, Malaysia (Male)
11. SMITH, MARTYN THOMAS, USA (Male)
12. VON BRAUN, MARGRIT, USA (Female)
13. WRIGHT, ROBERT ORRIN, USA (Male)

Note: WILD, CHRIS, UK (Male) was elected to membership and declined the offer due to his current position as Director of IARC.

**FELLOWS ELECTED IN 2011 (11 total: 9 men, 2 women)**

1. BLANC, PAUL D., USA (Male)
2. CHEN, JIA, China/USA (Female)
3. EASTMOND, DAVID, USA (Male)
4. FINKELSTEIN, YORAM Israel (Male)
5. JEEBHAY, MOHAMED, South Africa (Male)
6. KANG, SEONG-KYU, Korea (Male)
7. LAMBERTINI, LUCA, Italy (Male)
8. NEMERY DE BELLEVAUX, BENOIT, Belgium (Male)
9. SHENG WANG, China (Male)
10. SOTO, ANA, USA/Argentina (Female)
11. YOKOYAMA, KAZUHITO, Japan (Male)

**FELLOWS ELECTED IN 2010 (10 TOTAL: 5 men, 5 women + 1 emeritus)**

1. EMBER, ISTAVAN, Hungary (Male) - *deceased*
2. ETZEL, RUTH ANN, USA (Female)
3. HARRISON, ROBERT J., USA (Male)
4. KOVATS, SARI, UK (Female)
5. LABORDE, AMALIA Uruguay (Female)
6. STAYNER, LESLIE THOMAS, USA (Male)
7. TUNCER, APTULLAH MURAT, Turkey (Male)
8. WELSH, LAURA, USA (Female)
9. WICKRAMATILLAKE, HEMANTHA D., Sri Lanka (Male)
10. ZEISE, LAUREN, USA (Female)

and special Emeritus member: TERRACINI, BENEDETTO, Italy (Male)

**FELLOWS ELECTED IN 2009 (5 TOTAL: 3 men, 2 women)**

1. BIRNBAUM, LINDA, USA (Female)
2. DONNELLY, THOMAS, Ireland (Male)
3. HA, EUN-HEE, Korea (Female)
4. KOGI, KATZUTAKA, Japan (Male)
5. NORDBERG, GUNNAR, Sweden (Male)

FELLOWS OF THE COLLEGIUM RAMAZZINI  
OCTOBER 2014

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**PBI / Ex. 4**

# PBI / Ex. 4

## COLLEGIUM RAMAZZINI

### ENDOCRINE DISRUPTING CHEMICALS IN THE EUROPEAN UNION

The Collegium Ramazzini is an international scientific society that examines critical issues in occupational and environmental medicine with a view towards action to prevent disease and promote health. The Collegium derives its name from Bernardino Ramazzini, the father of occupational medicine, a professor of medicine of the Universities of Modena and Padua in the late 1600s and the early 1700s. The Collegium is comprised of 180 physicians and scientists from 35 countries, each of whom is elected to membership. The Collegium is independent of commercial interests.

#### ABSTRACT

*Europeans are exposed to Endocrine Disrupting Chemicals (EDCs), both natural and synthetic, to an extent that is causing adverse health effects. They include serious conditions like testicular, breast and prostate cancers, decline in sperm counts, pregnancy loss, puberty abnormalities, reproductive organ deformities, neurological problems, diabetes and obesity. Recent research suggests that the EDC effects can even be transmitted to future generations. The Collegium Ramazzini therefore urgently calls for new ways to test chemicals and to revise current approaches to risk management. In regard to the REACH authorization, the Collegium Ramazzini recommends improved test protocols and expanded test requirements to allow identification of EDCs, for which a safe threshold cannot be determined at present. Thus, the scope of REACH art 60(3) should be extended by default to all EDCs as substances of very high concern. Stringent hazard based cut-off criteria must be used for EDCs. In this process, GLP studies should not be considered the only basis for risk assessment, which must consider all academic research of high quality. Only in this way can the EU satisfy the requirement for a precautionary approach that will protect the general population and workers against these serious hazards.*

#### STATEMENT

Endocrine disrupting chemicals (EDCs) are synthetic or natural compounds that can cause disease and dysfunction by interfering with the action of the natural hormones in the human body that regulate growth, development, reproduction and aging and influence risk of cancer. Examples of synthetic EDCs include phthalates, bisphenol A, perchlorate, certain pesticides, brominated flame retardants, certain metals and dioxins. Chemicals with endocrine disrupting properties are manufactured in volumes of millions of tonnes per year and are widespread in consumer products such as soaps, shampoos, perfumes, electronics, textile and foam furnishings and plastics. They are common contaminants in air, food and drinking water. Evidence grows that exposure to EDCs in the places that we work, learn, live, and play is significant. National biomonitoring surveys document that that we all carry EDCs in our bodies.

The body of evidence on the health impacts of endocrine disrupting chemicals (EDCs) is substantial and increasing. Several recent reports have summarized the known and likely effects of these chemicals which include increased risks for testicular, breast and prostate cancers, decline in sperm counts, feminization *in utero* of newborn baby boys, pregnancy loss and

shortened gestational age, early puberty, reproductive organ deformities, neurological problems, diabetes and obesity. Early life stages including fetal, neonatal, and childhood development are particularly vulnerable to EDCs. Exposures in early life to EDCs can trigger onset of diseases in childhood and also later in life. EDC exposures can also affect the subsequent generations by causing alterations in gene expression in germ line cells (eggs and sperm).

The European Union (EU) is currently revising its EDC strategy. The European Parliament has voted a Resolution stressing the need for prompt action to protect public health, in accordance with the precautionary principle, and asked for reduction of exposure and improvements in the EU regulatory system. Several EU member states have already banned or announced intentions to ban certain uses of EDCs. These decisions to protect public health have been made on the basis of existing science. Currently criteria for identifying and assessing EDCs are under development and should apply across all relevant EU laws. The mandate to develop these criteria is given in the pesticides and biocides regulations (Regulation 07/2009 and 528/2012), and the Criteria must be proposed (for pesticides) or adopted (for biocides) by December 2013. The Pesticides and Biocide laws include a cut-off scheme that eliminates EDCs (with certain exemptions). Also, the review of how the substances should be treated by the REACH authorisation process requires a decision on whether a threshold level for effects can be determined for EDCs or not. If an expansion of the scope of REACH article 60(3) to include EDCs seems justified, authorisation for the use of EDCs identified under REACH can be granted only if it can be demonstrated that the socio-economic benefits outweigh the risks to human health, or the environment, and if there are no suitable alternative substances or technologies.

In view of these policy opportunities and the need for action, the Collegium Ramazzini recommends the following:

**Improve Testing Protocols and Testing Requirements.** As recently concluded by the WHO/UNEP, the internationally agreed and validated test methods capture only a limited range of the known spectrum of endocrine disrupting effects and are inadequate to detect endocrine disrupting effects that are linked to many human diseases. This increases the likelihood of harmful effects in humans and wildlife being overlooked. Further testing will be needed to identify biologically significant effects including low dose effects, effects from early life-stage exposures, non-monotonic dose response curves, impact of chemical mixtures, or behavioral and cognitive effects that are often missed with traditional toxicity testing. The testing requirements of EU legislation would need to be expanded so that adequate data are generated. Such data needs will likely require both animal testing and use of alternative methods. Sprague Dawley rat models, which are already in use for carcinogenicity bioassays and for the Endocrine Disruptor Screening Program of the EPA, seem to be particularly appropriate. A more realistic risk assessment should include prenatal exposures and prolonged observation of experimental animals at least up to 130 weeks.

**Include Academic research as a basis for risk assessment.** Government and public health agencies should not rely only, or even preferentially, on GLP studies. The selection of evidence for good quality risk assessment by government and public health agencies must include academic research, published in respected scientific journals after a peer-review process and publicly accessibly, in addition to consideration of studies conducted according to established “Good Laboratory Practices” (GLP) criteria.

It is important to recognize that GLP requirements are merely *de minimis* criteria and not a seal of scientific excellence. They are designed to set a baseline of cleanliness, animal care, and record-keeping. They are not associated with higher quality research, proper study design or correct statistical analysis. In fact, GLP study designs are often very outdated and do not reflect the current science, most sensitive disease endpoints, or chronic disease outcomes. In contrast, most academic research reflects current scientific advances, has been published in respected scientific journals and relies on the peer-review process and public accessibility to uphold scientific quality.

**Extend the scope of REACH art 60(3) by default to all EDCs identified as substances of very high concern.** EDCs are to be regarded as substances for which it is not possible to determine a safe threshold for adverse effects and adequately control the risks. They have been shown capable of causing injury to the developing human brain and reproductive organs at the lowest levels detectable, levels far below those that harm adults, particularly if the exposure occurs during a critical developmental window. Unlike traditional environmental toxicants in which the risk of adverse events increases as the exposure levels increase, endocrine disruptors may exert effects at both low doses as well as high doses.

**Define strict cut-off criteria, based on hazard assessment.** Deriving an exposure dose that may be considered safe and assessing risk cannot be carried out with a satisfactory level of certainty due to the occurrence of adverse effects at low doses; the existence of non-monotonic dose response curves; co-exposures to a whole range of chemicals which may affect the same adverse outcome; irreversibility; exposure during critical stages of development; and of early life exposure and onset of diseases later in life. Therefore stringent hazard based cut-off criteria for identifying and assessing EDCs are justified.

**Apply the precautionary principle and respond to early warning signals.** The precautionary principle provides justification for acting in the face of uncertainty, as a tool for acting on the basis of early warnings. While support for targeted research is a high priority, the need for further research should not delay necessary policy and regulatory decisions to protect public health. Accordingly, technologies are no longer presumed safe simply because evidence of risk or adverse effect is unavailable. Precautionary approaches presume that an induced adverse response in animals is a reliable indicator of potential harm in humans, unless informed otherwise by multiple well-designed and well-conducted studies. The EU Treaty includes the precautionary principle. Also the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) from 1995 allows provisional measures “on the basis of available pertinent information.

**Reduce exposure.** The possible public health implications of exposures and the uncertainties in risk assessment as mentioned above highlight the need to reduce exposure to EDCs and to replace them with safer alternatives whenever available.

**Monitor exposure.** Monitoring of the general population, workplaces and workers in the EU for exposure to EDCs and for possible effects should support and evaluate regulatory control measures. Recent human biomonitoring studies from across Europe addressing a limited number of biomarkers have shown EDCs in both children and their mothers.



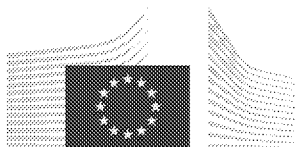
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EUROPEAN COMMISSION

Assistant to the Chief Scientific Adviser

Brussels, 24/10/2013

## **Minutes of the expert meeting on endocrine disruptors**

Date: 24/10/2013, 14:00-17:00

Venue: Office of the Chief Scientific Adviser, European Commission, Berlaymont Building, Brussels

Participants: Anne Glover (Chair), Anna Maria Andersson (Expert), Alan Boobis (Expert), Wolfgang Dekant (Expert), Helmut Greim (Expert), Ulla Hass (Expert), Andreas Kortenkamp (Expert), Jan Marco Müller (Rapporteur), Didier Schmitt (Rapporteur)

Following a quick *tour de table* in which each participant presented her/himself, the Chair outlined the purpose and scope of the meeting, that is to discuss the science of endocrine disruptors in order to identify both scientific consensus and dissent. The Chair stressed that the meeting would not address any policy considerations.

The participants quickly agreed that there is no major controversy in science around the definition of endocrine disrupting chemicals (EDCs). All can agree upon the definition provided by the WHO, which is also used by EFSA. Substances can act either directly or indirectly on the endocrine system, which are being discussed as part of the criteria, but this does not affect the baseline definition of EDCs.

### **Thresholds**

There was agreement that thresholds need to be differentiated between thresholds *in vitro*, at the level of an organism, and at population level.

The participants discussed the concept of “no observed adverse effect level” (NOAEL), commonly used by regulatory bodies. There was agreement that this is not to be understood as a “zero effect level” as it depends on the study design (e.g. sensitivity of instruments, number of animals used, dose spacing, etc.).

There was agreement that the existence of thresholds cannot be determined experimentally. For this it would be necessary to look at much smaller doses, with correspondingly smaller effects, beyond the resolving power of toxicological experiments. It is therefore uncertain whether there are thresholds at all, at least for some endpoints. For genotoxic chemicals it is widely accepted that there are no thresholds, this insight not being derived from experiments, but from a better understanding of the mechanisms by which these agents work. The participants agreed that similar considerations will be important in connection with EDCs. The scientific debate on whether there are biological thresholds for EDCs is on-going.

An important point made was that for many chemicals zero exposure does not exist – in fact, all organisms have a background exposure to a range of chemicals, so it is essential to understand how an EDC contributes to and interacts with this background. One group of experts stressed that thresholds cannot exist if there are internal exposures to substances that already show effects, as is the case for the endogenous oestrogens and androgens. In these cases, any external exposure to EDCs will add to the effect of the internal background, with no threshold. According to this group EDCs interact with an already active system (endogenous hormones present).

The other scientific group stated that there is a high likelihood that thresholds regarding EDCs exist and that behaviour of EDCs can be predicted based on mechanisms. If an EDC with low potency has a relatively low concentration compared to the endogenous compound, it will bind less to the receptor and therefore have less potency effect. As binding affinity is an intrinsic property of a chemical, a compound with low affinity will require much higher concentrations to induce an effect. Therefore, a low potency compound, if present in low concentrations, may have very little effect, such as an increase in receptor occupancy from 50 to 50.01 %. According to this group, it is highly questionable if such small changes in receptor occupancy will result in a biologically relevant change.

The participants agreed that whether or not such exposures are of sufficient magnitude to warrant concern, is a matter for risk assessment. In this connection, consideration of potency, together with exposure, is important; potent compounds in low concentration may have the same effects as less potent compounds at higher concentrations. To achieve more clarity about EDCs and thresholds it is necessary to improve our understanding of mechanisms, e.g. by taking a systems-based approach.

### **Non-monotonic dose-response relationships**

There was agreement that non-monotonic dose-response curves exist, but have been observed only occasionally. The participants agreed that dose-dependent changes in the mechanisms of EDCs can give rise to non-monotonic dose-response relationships. The question is how often adverse non-monotonic effects occur, in which dose range they are observed, and what implications this might have in testing for regulatory purposes.

In fact, there are indications that for some endpoints there is a clear non-monotonic dose response at high concentrations. There was no consensus whether such responses also occur at low concentrations and how often this is the case. The EPA report on EDCs did not identify a non-monotonic dose-response regarding adverse effects in low dose ranges. There are cases of U-shaped dose-response curves for essential metals, vitamins, and other chemicals. One view was that non-monotonic dose-response curves may be the result of the superimposition of different monotonic dose-response curves, and that these would both be characterised using existing test strategies. However, others argued this is not the case and that it is not possible to anticipate reliably when a dose-response relationship will be non-monotonic.

## Testing strategies

A key issue is how to design testing strategies that ensure that all non-monotonic relationships are adequately captured. There are disagreements over the question whether the existence of non-monotonic dose-response relationships will have to trigger major changes in the regulatory testing of chemicals. There are some study designs proposed to find non-monotonic effects, but they are not yet agreed upon.

There are many different approaches to testing for endocrine disrupting effects and different regulations have different requirements. Testing in the context of regulation relies on internationally validated tests for EDCs and there was agreement among the participants that the OECD has contributed a great deal in this area. There is now a large number of validated OECD tests available allowing detection of effects on the endocrine system, but the endpoints may not yet cover all potential adverse effects of EDCs.

Very few validated OECD tests for endocrine disrupting effects have been implemented in the testing requirements within EU legislation so far. To identify EDCs reliably, it is necessary to test for adversity and an endocrine mode of action. Many chemical companies do this already, but it is not yet demanded by legislation, nor are such data publicly available. For example, REACH does not reflect the new OECD guidelines yet (and in any case testing requirements do not cover chemicals below a certain production tonnage).

## Other issues

The impact of EDCs on the early development stage of organisms where disruption might cause irreversible damage (“window of vulnerability”) was mentioned as a key concern. There was agreement that the impact on reproductive development is indeed an important issue.

Some of the experts drew attention to recent epidemiological studies having shown a so far unknown effect of paracetamol on male fetuses in pregnant women. Whilst the biological effects of paracetamol were well-known, the developmental findings were unexpected. Paracetamol has been on the market for a long time, but was never tested for this particular effect. Other experts stated that there are publications contesting this link and took the view that whilst there were sensitive developmental stages, this did not mean that the fetus was unprotected from possible effects of maternal exposure to EDCs.

There was agreement that potency and exposure (and their likelihood) are key elements to be considered in risk assessments. Some experts were of the view that substances must be clearly labelled when they are endocrine disruptors of high potency, to ensure adequate protection of the public. Other experts stated that potency and exposure are not topics to be considered when it comes to *hazard* identification of substances as endocrine disruptors for the purpose of EU regulations.

The participants agreed that there is a need for the development of further assays and tests to cover “blind spots”. One such “blind spot” concerns the identification of substances that might cause hormonal cancers such as breast, testis or prostate cancer. These cancers have increased in Europe over the last few decades, but it is not clear whether this is related to exposure to EDCs or other factors such as life-style. One group expressed that well-established clinical experience of hormone disorders and cancer points to a strong link between the adverse effects observed in the population and disturbances of the endocrine system. There are early signals in experimental studies that might highlight specific risks on longer term exposure. It should be noted that

carcinogenic studies are expensive, labour-intensive and cannot be done on a routine basis for a large number of chemicals, thus being requested by REACH only above 1000t production level.

There was consensus that it is a responsibility of scientists to flag where evidence suggests that crucial endpoints might have been overlooked. This needs to be taken into account when designing future research programmes and related priorities. It is necessary to build up a solid evidence base that can inform policy-makers.

Science and policy-making on EDCs are at a paradigm shift. Public and political pressure asks for less testing of animals in risk assessments. At the same time, there is a clear need for more evidence regarding EDCs, in particular their impact on different development stages of organisms as well as mixture effects. Making a trade-off between these goals is ultimately an issue for societal debate, in which science has a key role to play.

The meeting finished with an agreement of all participants on a set of conclusions (see annex).

The Chair expressed how much she enjoyed the scientific discussion and thanked all participants for their efforts to come to Brussels and contribute in such a constructive manner to this interesting debate.

*Jan Marco Müller, 24/10/2013*

## Meeting on endocrine disruptors

Office of the Chief Scientific Adviser, European Commission, Brussels, 24.10.2013

### Conclusions agreed by the participants

1. The participants appreciate the initiative of the Chief Scientific Adviser to help discuss the remits of scientific consensus around issues on endocrine disrupting substances (EDCs).
2. EDCs are a good example where scientific advice is an essential element for environment and health related policy-making.
3. There is substantial agreement as well as uncertainty on scientific issues around EDCs. Some of the main consensus and uncertainties are as follows:
  - a. Definition
    - There is good agreement on the definition of EDCs based on WHO-IPCS of 2002 and EFSA 2013.
    - The definition has to be interpreted in relation to the EDC criteria, to disturbance of homeostasis and to developmental stages issues.
  - b. Thresholds
    - It is possible that thresholds do not exist; the reason of the uncertainty is the limitation of the experimental constraints and the understanding of the biology.
    - It is not possible to define thresholds only by experiments in whole organisms due to lack of sensitivity.
    - The existence of thresholds must be defined by understanding better the mechanisms of action in a quantitative systems approach.
  - c. Non-monotonicity
    - Non-monotonic effects do exist for some EDCs *in vitro* or *in vivo*.
    - The question is how often adverse non-monotonic effects occur.
    - Non-monotonic effects may derive from different mechanisms working together or against each other.
  - d. Testing
    - The currently validated OECD guidelines may not cover all potential adverse effects or modes of action of EDCs.
    - Improved study designs to find possible non-monotonic effects are available, but not yet agreed.
    - More dedicated methods are needed to evaluate possible effects relevant for humans, especially for hormonal cancer induction or long-term effects.

### Participants

*Experts:* Anna-Maria Andersson, Alan Boobis, Wolfgang Dekant, Helmut Greim, Ulla Hass, Andreas Kortenkamp

*Chair:* Anne Glover, CSA

*Rapporteurs:* Jan Marco Müller and Didier Schmitt (BEPA/CSA Office)